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09/867,475	05/31/2001	Monika Lusky	017753-146	7808
21839	7590	10/01/2003	EXAMINER	
BURNS DOANE SWECKER & MATHIS L L P			MARVICH, MARIA	
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ALEXANDRIA, VA 22313-1404			PAPER NUMBER	
			1636	17

DATE MAILED: 10/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/867,475

Applicant(s)

LUSKY ET AL.

Examiner

Maria B Marvich, PhD

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 22 July 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) 32-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3,4,6-30,32,36 and 37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 May 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 09/463,486.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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### DETAILED ACTION

This Office Action is in response to an amendment filed 7/22/03, Paper No. 16. Claims 2 and 5 have been cancelled. Claims 36-37 have been added. Claims 1, 3, 11, 13, 16, 21-22 and 26 have been amended. Claims 1, 3-4 and 6-37 are pending in this application. Claims 31 and 33-35 have been withdrawn from consideration.

#### *Double Patenting*

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 3, 6, 8, 11, 20-21, 25-27 and 36 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 23 and 25-29 of U.S. Patent No. 6,479,290. **The rejection of claims 1, 3, 6, 8, 20, 21 and 25-27 is maintained for reasons of record in the office action filed 4/22/03 and restated below. This rejection is extended to newly added claim 36. The new rejection of claim 11 is necessitated by amendment.**

Although the conflicting claims are not identical, they are not patentably distinct from each other because the examined claims are either anticipated by, or would have been obvious

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over the reference claims. Claim 23 of the US patent 6,479,290 recites a method for preparing a replication defective recombinant adenovirus (rAd) using two helper virus of which one comprises a heterologous encapsidation sequence introduced into a first cell line. Viral particles comprising both helper viruses are recovered and introduced with the rAd into a second cell line. Claim 25 recites that the other helper is from a bovine adenovirus genome and claim 26 that it is also defective for E1. The first cell line, according to claim 27, is an MDBK or primary bovine cell line and according to claim 29, the second cell line is 293. Claims 23 and 25-29 of US patent 6,479,290 are the same as those in claims 1-3, 6, 8, 11, 20-21, 25-27 and 36 of the instant application but the claims differ in that the method claims of the instant application recite that the rAd is a minimal adenoviral vector and the bovine adenoviral genome is BAV3. A minimal

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adenoviral vector is fully anticipated by claim 23 of US patent 6,479,290 in that recites is a replication defective rAd. Using the specification as a dictionary, (column 4, line 25-26) the bovine adenoviral genome disclosed is BAV3. Therefore, it would have been obvious to modify the method claims of US patent 6,479,290 such that the bovine adenoviral genome is BAV3. One of ordinary skill in the art would have been motivated to make such a modification as it is disclosed to be the only bovine adenoviral genome contemplated by the invention.

Additionally, if a patent resulting from the instant claims was issued and transferred to an assignee different from the assignee holding the 6,479,290 patent, then two different assignees would hold a patent to the claimed invention of 6,479,290, and thus improperly there would be possible harassment by multiple assignees.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3-4, 6-30, 32 and 36-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. **This rejection is maintained for reasons of record in the office action filed 04/22/03 and restated below. This rejection is extended to newly added claims 36 and 37.**

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Claims 1 is vague for reciting a genome of (ii) "deriving from" the second adenovirus genome. It is unclear how closely related the derived sequences are to the original adenovirus and it is also unclear what the functional and structural relationship between the original adenovirus and vectors "derived from" said adenovirus are. The metes and bounds of the claimed subject are unclear.

The term "different" in claim 1 is a relative term, which renders the claim indefinite. The term "different" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The metes and bounds of the claim cannot be established.

Regarding claims 30 and 32 the phrase "substantially" renders the claim indefinite. The term "substantially" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The metes and bounds of this claim cannot be established.

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In the previous office action filed 4/22/03, Paper No. 15, it was mistakenly noted that this rejection encompassed claims 29 and 32 whereas the rejection should have stated that claims 30 and 32 were rejected.

*Response to Argument*

In the amendment filed 7/22/03, Paper No. 16, applicants stated that they would file a terminal disclaimer disclaiming the terminal part of the statutory term of any patent granted on the instant application, which would extend beyond the expiration date of U.S. Patent No. 6,479,290. Until receipt of said Terminal Disclaimer, the claims stand as rejected.

Applicant argues on page 13-14 of the amendment filed 7/22/03, that by incorporation of "wherein said first adenovirus is an animal adenovirus and second adenovirus is a human adenovirus" into claim 1 clarifies use of the term "different".

Applicant's arguments filed 7/22/03 have been fully considered but they are not persuasive. While it has been clarified that the genome of the first and second helper genomes are at least different in origin, it is unclear if this is the sole difference between the two genomes. Does the genome of (ii) differ by one or one hundred or one thousand nucleotides or differ in the method of isolation of genome (i).

Applicant argues on page 15-16 that the term "substantially" is used to be consistent with the limitations of the available methods to detect helper virus. Applicants state that it is impossible to detect one helper virus in a high titer viral stock.

Applicant's arguments filed 7/22/03 have been fully considered but they are not persuasive. The term "substantially" is used to convey that the viral stocks obtained by the

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methods of the invention are free of vector to the extent that helper free virus can be detected in a sample. However, as "substantially" is a relative term and is not defined in the specification and for which there is no art recognized definition, the metes and bounds of the viral preparation are unknown. This in turn renders the claim vague and indefinite.

It is noted that applicants have defined "approximately" on page 14-15 of the amendment filed 7/22/03 to mean that the nucleotide sequence has one or a few nucleotides beyond the extremities of the recited one.

*Conclusion*

No claims are allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria B Marvich, PhD whose telephone number is (703) 605-1207. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, PhD can be reached on (703) 305-1998. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Maria B Marvich, PhD  
Examiner  
Art Unit 1636

MM

  
TERRY MCKELVEY  
PRIMARY EXAMINER

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